K082917

1072

Medtronic Sofamor Danek
MASTERGRAFT® Resorbable Ceramic Granules
510(K) Summary
September 2008

I. Company: **Medtronic Sofamor Danek USA**
1800 Pyramid Place
Memphis, TN 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738

JAN - 9 2009

Contact: **Ryan Massey**
Regulatory Affairs Specialist

II.Proposed Proprietary Trade Name:	MASTERGRAFT Resorbable Ceramic Granules
Classification Name:	Bone grafting material
Product Code:	NUN
Regulation No.:	872.3930

III. Product Description/Purpose of Application

MASTERGRAFT® Resorbable Ceramic Granules is made of medical grade combination of hydroxyapatite and b-tricalcium phosphate. MASTERGRAFT® is provided in a 60 percent hydroxyapatite and 40 percent b-tricalcium phosphate formulation. Alternatively, MASTERGRAFT® may be provided in a 15 percent hydroxyapatite and 85 percent b-tricalcium phosphate formulation. The product is supplied sterile for single patient use. MASTERGRAFT® Resorbable Ceramic Granules is an osteoconductive porous implant.

The purpose of this 510(k) application is to expand the indications for the MASTERGRAFT® Resorbable Ceramic Granules device so that it may be used in the oral and maxillofacial region. Like the previously cleared predicates, MASTERGRAFT® Resorbable Ceramic Granules (K020986, SE 07/22/2002) and MBCP™ (K051885, SE 09/16/2005), the subject system is intended to be used alone or combined with autograft as a bone void filler for bony voids or gaps that are not intrinsic to the stability of the bony

structure. In addition, MASTERGRAFT® Resorbable Ceramic Granules can be mixed with autograft and used as a bone graft extender.

IV. Indications

MASTERGRAFT® Resorbable Ceramic Granules may be used alone or in combination with autograft to provide a bone void filler that is resorbed/remodeled and is replaced by host bone during the healing process. MASTERGRAFT® Resorbable Ceramic Granules is packed into bony voids or gaps to fill and/or augment dental oral/maxillofacial bony tissue. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Procedures include:

- Filling of periodontal defects
- Filling of dental extraction sockets
- Filling of cystic defects
- Sinus lifts
- Alveolar ridge augmentation
- Oral/maxillofacial augmentation or reconstruction.

MASTERGRAFT® Resorbable Ceramic Granules may be used with or without internal fixation, and may be mixed with autograft as a bone graft extender.

V. Substantial Equivalence

Documentation is provided that demonstrates MASTERGRAFT® Resorbable Ceramic Granules to be substantially equivalent to the previously cleared MASTERGRAFT® Resorbable Ceramic Granules (K020986, SE 07/22/2002) and MBCP™ (K051885, SE 09/16/2005).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 26 2009

Mr.Ryan Massey
Regulatory Affairs Specialist
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K082917/A001
Trade/Device Name: Mastercraft Resorbable Ceramic Granules
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone grafting material
Regulatory Class: II
Product Code: LYC
Dated: January 27, 2009
Received: January 28, 2009

Dear Mr. Massey:

This letter corrects our substantially equivalent letter of January 9, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-***[see OC organization structure below for correct phone extension].*** Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Ginette Y. Michaud M.D.

Ginette Y. Michaud, M. D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K082917

Device Name: MASTERGRAFT® Resorbable Ceramic Granules

Indications for Use:
MASTERGRAFT® Resorbable Ceramic Granules may be used alone or in combination with autograft to provide a bone void filler that is resorbed/remodeled and is replaced by host bone during the healing process. MASTERGRAFT® Resorbable Ceramic Granules is packed into bony voids or gaps to fill and/or augment dental oral/maxillofacial bony tissue. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Procedures specific to MASTERGRAFT® Granules include:
- Filling of dental extraction sockets
- Filling of cystic defects
- Oral/maxillofacial augmentation or reconstruction.

Procedures specific to MASTERGRAFT® Mini Granules include:
- Filling of periodontal defects
- Sinus lifts
- Alveolar ridge augmentation
- Filling of dental extraction sockets
- Filling of cystic defects
- Oral/maxillofacial augmentation or reconstruction.

MASTERGRAFT® Resorbable Ceramic Granules may be used with or without internal fixation, and may be mixed with autograft as a bone graft extender.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X___ OR Over-The-Counter Use _____
Per 21 CFR 801.109

Robert B Ochs DDS for Dr. Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082917